have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996]

§ 884.1730 Laparoscopic insufflator.

(a) *Identification.* A laparoscopic insufflator is a device used to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

(b) *Classification.* (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments which are not used to effect intra-abdominal access, Verres needles etc.; and single-use tubing kits used for only intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 61 FR 1124, Jan. 16, 1996]

Subpart C—Obstetrical and Gynecological Monitoring Devices

§ 884.2050 Obstetric data analyzer.

(a) *Identification.* An obstetric data analyzer (fetal status data analyzer) is a device used during labor to analyze electronic signal data obtained from fetal and maternal monitors. The obstetric data analyzer provides clinical diagnosis of fetal status and recommendations for labor management and clinical interventions. This generic type of device may include signal analysis and display equipment, electronic interfaces for other equipment, and power supplies and component parts.

(b) *Classification:* Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before October 3, 2000, for any obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976, or that has been found, on or before October 3, 2000, to be substantially equivalent to an obstetric data analyzer described in paragraph (a) of this section that was in commercial distribution before May 28, 1976. Any other obstetric data analyzer described in paragraph (a) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

[65 FR 41332, July 5, 2000]

§ 884.2225 Obstetric-gynecologic ultrasonic imager.

(a) *Identification.* An obstetric-gynecologic ultrasonic imager is a device designed to transmit and receive ultrasonic energy into and from a female patient by pulsed echoscopy. This device is used to provide a visual representation of some physiological or artificial structure, or of a fetus, for diagnostic purposes during a limited period of time. This generic type of device may include the following: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, coupling gel, and component parts. This generic type of device does not include devices used to monitor the changes in some physiological condition over long periods of time.

(b) *Classification.* Class II (performance standards).

§ 884.2600 Fetal cardiac monitor.

(a) *Identification.* A fetal cardiac monitor is a device used to ascertain fetal heart activity during pregnancy and labor. The device is designed to separate fetal heart signals from maternal heart signals by analyzing electrocardiographic signals (electrical potentials generated during contraction

and relaxation of heart muscle) obtained from the maternal abdomen with external electrodes. This generic type of device may include an alarm that signals when the heart rate crosses a preset threshold. This generic type of device includes the ''fetal cardiotachometer (with sensors)'' and the ''fetal electrocardiographic monitor.''

(b) *Classification.* Class II (performance standards).

§ 884.2620 Fetal electroencephalographic monitor.

(a) *Identification.* A fetal electroencephalographic monitor is a device used to detect, measure, and record in graphic form (by means of one or more electrodes placed transcervically on the fetal scalp during labor) the rhythmically varying electrical skin potentials produced by the fetal brain.

(b) *Classification.* Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before December 26, 1996 for any fetal electroencephalographic monitor that was in commercial distribution before May 28, 1976, or that has, on or before December 26, 1996 been found to be substantially equivalent to a fetal electroencephalographic monitor in commercial distribution before May 28, 1976. Any other fetal electroencephalographic monitor shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[45 FR 12684–12720, Feb. 26, 1980, as amended at 52 FR 17741, May 11, 1987; 61 FR 50708, Sept. 27, 1996]

§ 884.2640 Fetal phonocardiographic monitor and accessories.

(a) *Identification.* A fetal phonocardiographic monitor is a device designed to detect, measure, and record fetal heart sounds electronically, in graphic form, and noninvasively, to ascertain fetal condition during labor. This generic type of device includes the following accessories: signal analysis and display equipment, patient and equipment supports, and other component parts.

(b) *Classification.* Class II (performance standards).

§ 884.2660 Fetal ultrasonic monitor and accessories.

(a) *Identification.* A fetal ultrasonic monitor is a device designed to transmit and receive ultrasonic energy into and from the pregnant woman, usually by means of continuous wave (doppler) echoscopy. The device is used to represent some physiological condition or characteristic in a measured value over a period of time (e.g., perinatal monitoring during labor) or in an immediately perceptible form (e.g., use of the ultrasonic stethoscope). This generic type of device may include the following accessories: signal analysis and display equipment, electronic interfaces for other equipment, patient and equipment supports, and component parts. This generic type of device does not include devices used to image some relatively unchanging physiological structure or interpret a physiological condition, but does include devices which may be set to alarm automatically at a predetermined threshold value.

(b) *Classification.* Class II (performance standards).

§ 884.2675 Fetal scalp circular (spiral) electrode and applicator.

(a) *Identification.* A fetal scalp circular (spiral) electrode and applicator is a device used to obtain a fetal electrocardiogram during labor and delivery. It establishes electrical contact between fetal skin and an external monitoring device by a shallow subcutaneous puncture of fetal scalp tissue with a curved needle or needles. This generic type of device includes nonreusable spiral electrodes and reusable circular electrodes.

(b) *Classification.* Class II (performance standards).

§ 884.2685 Fetal scalp clip electrode and applicator.

(a) *Identification.* A fetal scalp clip electrode and applicator is a device designed to establish electrical contact between fetal skin and an external